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Re-evaluation Decision RVD2021-01

Tebufenozide and Its Associated End-use Products

Final Decision

(publié aussi en français) **21 January 2021**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2021-1E (print version)
H113-28/2021-1E-PDF (PDF version)

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Re-evaluation decision for tebufenozide and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Tebufenozide is an insect growth regulator used to control Lepidoptera larvae on apples, pears, ornamental crab apple trees, berries, greenhouse vegetables, greenhouse ornamentals, and forests and woodlots (restricted use). Tebufenozide is applied using ground and aerial equipment. Tebufenozide is registered for commercial use and can be used in residential areas by commercial applicators on trees. Currently registered products containing tebufenozide can be found in the Pesticide Label Search and in Appendix I. The Proposed Re-evaluation Decision PRVD2019-06, *Tebufenozide and its Associated End-Use products*[1] containing the evaluation of tebufenozide and proposed decision, underwent a 90-day consultation period ending on 9 September 2019. PRVD2019-06 proposed that products containing tebufenozide are acceptable for continued registration in Canada, provided that the risk mitigation measures are in place.

Health Canada received comments and information relating to the health and environmental assessments. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments and new data did result in revisions to the environmental risk assessments (see Science Evaluation Update), and did result in changes to the proposed re-evaluation decision as described in PRVD2019-06.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2019-06, and further information used in the re-evaluation decision is listed in Appendix VI of this RVD. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in the Reference List of the PRVD2019-06 and the information set out in Appendix VI herein.

This document presents the final re-evaluation decision[2] for the re-evaluation of tebufenozide, including the required amendments (risk mitigation measures) to protect human health and the environment, and any label amendments required to bring labels to current standards. All products containing tebufenozide that are registered in Canada are subject to this re-evaluation decision.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Re-evaluation decision for tebufenozide

Health Canada has completed the re-evaluation of tebufenozide. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing tebufenozide is acceptable. An evaluation of available scientific information found that uses of tebufenozide products meet current standards for protection of human health and the environment when used according to revised label directions, which include mitigation measures. Label amendments, as summarized below and listed in Appendix V, are required.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of tebufenozide, are summarized below. Refer to Appendix V for details.

Human health

Label improvements to meet current standards:

- Updated label statements for personal protective equipment, restricted-entry intervals and those related to spray drift and bystanders.

Environment

Risk mitigation:

To protect the environment, the following risk-reduction measures are required:

- Standard label statement to inform users of the potential toxic effects of tebufenozide to sediment-dwelling aquatic invertebrates.
- Spray buffer zones (up to 15 m) to protect aquatic habitats (Appendix V, Table 1).
- To reduce the potential for runoff of tebufenozide to adjacent aquatic habitats, precautionary label statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted.

Next steps

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels.

Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection[3] regarding this decision on tebufenozide and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

The relevant test data on which the decision is based (as referenced in PRD2019-06 and in Appendix VI of this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act.*

Science evaluation update

1.0 Health risk assessment

1.1 Toxicology summary

Details of the toxicological assessment can be found in PRVD2019-06. A single toxicology-related comment was received during consultation, from the registrant, Nippon Soda Company Ltd. Following critical analysis of the registrant's comment and the available toxicology data for tebufenozide, Health Canada maintains that the tebufenozide toxicology database supports the acute oral reference value of 0.04 mg/kg bw outlined in PRVD2019-06. The toxicology reference values for tebufenozide presented in PRVD2019-06 remain unchanged (see Appendix IV).

The detailed response to the comment received is provided in Appendix III.

1.2 Exposure and risk assessment

The health risk assessment for tebufenozide (including dietary, occupational, non-occupational, aggregate and cumulative) was previously conducted and presented in PRVD2019-06. No comments were received on the health risk assessment during the consultation period. There were no changes made to the health risk assessment.

2.0 Revised environmental risk assessment

An aerobic biotransformation study (PMRA# 3033477) was submitted by the registrant and was found to be acceptable. Total system (water/sediment) DT_{50} values were estimated to be 79.1 and 213 days (T = 20 °C) using SFO kinetics for river and pond systems respectively. With the addition of these two DT_{50} values for tebufenozide, a total of four values were available to estimate an 80th percentile half-life for use in risk assessment (Table 1). Accordingly, the 80th percentile DT_{50} value of 162 days was estimated using the four available aerobic aquatic total system biotransformation DT_{50} values from two studies (Table 1). This value is slightly longer than the value used in the PRVD2019-06 (128 days).

Table 1 Aerobic aquatic Biotransformation of Tebufenozide

System	T (°C)	pH	Reported DT_{50} (days)	Calculated DT_{50} by the PMRA (days)	Kinetic model	Comments	PMRA #
Arkansas silty clay	25	6.9	99.0	107.0	SFO	Moderately persistent	1128844
California clay loam	25	7.8	101.0	128.0	SFO	Moderately persistent	
Rheinsulz river system	25	6.9	86.3	79.1	SFO	Moderately persistent	3033477
Ormalingen pond system	25	7.8	204.4	213	SFO	Moderately persistent	

In the PRVD2019-06, the endpoint used for buffer zone calculations was a 28-day NOEL (emergence) of 3.7 µg a.i./L for *Chironomus riparius* based on time-weighted average of measured water concentrations from a laboratory-based study (PMRA# 1172878). A new aquatic mesocosm study submitted by the registrant during the PRVD comment period (PMRA# 3033478) was found to be acceptable. Based on significant effects on chironomid species, a NOEL of 9.7 µg a.i./L was determined from this study and used to refine the toxicity endpoint. The outdoor mesocosm endpoint is derived from a more realistic scenario that focused on tebufenozide exposure to moulting aquatic organisms (in other words, insects and crustaceans within macroinvertebrates and zooplankton) in an outdoor exposure tank. The mesocosm NOEL of 9.7 µg a.i./L is for reduced abundance of chironomids at the end of the study (85 days), which supports the idea that this species is the most sensitive aquatic invertebrate to tebufenozide. As such the NOEL of 9.7 µg a.i./L was used to recalculate the buffer zones for the protection of aquatic life from tebufenozide use. Consequently, the aquatic buffer zones have been updated from those presented in the PRVD2019-06 and are presented in Appendix V.

No additional changes were made to the environmental risk assessment.

4.0 Value assessment

Tebufenozide is the only active ingredient registered to manage certain moth pests on apples, berries, ornamental crab apple trees, and greenhouse ornamentals. Therefore, tebufenozide is an important component of pest management programs aimed at reducing economic damage to crops and ornamental plants from moth infestations.

5.0 Conclusion of science evaluation

With respect to human health, risks associated with the use of tebufenozide and associated end use products are acceptable when these products are used according to revised label directions with the risk mitigation measures (see Appendix V).

The environmental risks associated with the use of tebufenozide and associated end use products are acceptable when used according to revised label directions with the risk mitigation measures outlined in Appendix V.

Use of tebufenozide is an important management tool for reducing economic damage to crops and ornamental plants from moth infestations.

List of abbreviations

ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
a.i.	active ingredient
bw	body weight
EFSA	European Food Safety Authority
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
F_0	parental generation
F_1	first generation
F_2	second generation
g	gram
GPS	global positioning system
ha	hectare
kg	kilogram
L	litre
mg	milligram
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No-Observed-Adverse-Effect-Level
NOEL	No-Observed-Effect-Level
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
REI	Restricted entry interval
RVD	Re-evaluation Decision
SFO	single first order
T	temperature
µg	microgram
USEPA	United States Environmental Protection Agency

Appendix I Registered tebufenozide products in Canada[1]

Table 1 Products requiring label amendments

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (%, g/L)
24501	Technical Grade Active Ingredient	Nippon Soda Company Ltd.	Tebufenozide Technical Insect Growth Regulator	Solid	97.1%
32440	Technical Grade Active Ingredient	Spray Industries Limited	Limit Technical Insecticide	Solid	99%
24502	Restricted	Nippon Soda Company Ltd.	Mimic 240LV Forestry Insecticide	Suspension	240 g/L
32535	Restricted	Spray Industries Limited	Limit 240 Forestry Insecticide	Suspension	240 g/L
24503	Commercial	Nippon Soda Company Ltd.	Confirm 240F Agricultural Insecticide	Suspension	240 g/L

[1] as of 14 May 2020, excluding discontinued products or products with a submission for discontinuation

Appendix II List of commenters to PRVD2019-06

List of commenter's affiliation for comments submitted in response to PRVD2019-06

Category	Respondent
Registrant	Nippon Soda Company Ltd.

Appendix III Comments and responses

Health Canada received two written comments during the public consultation for the tebufenozide proposed re-evaluation decision. Commenter's affiliation is listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them, are provided below.

1.0 Comment related to the health risk assessment

1.1 Toxicology

Comment related to the acute reference dose (ARfD)

The registrant suggested that the NOAEL of 89.4 mg/kg bw from the dog dietary acute hematotoxicity study (PMRA# 2702970) is preferable for derivation of the ARfD, rather than the offspring NOAEL of 12.8 mg/kg bw/day selected by Health Canada based on early postnatal loss in two co-critical rat dietary multi-generation reproductive toxicity studies (PMRA# 1128829, 1168364). In support of their position, the registrant indicated that the dog is the most sensitive species and referenced the tebufenozide toxicology summary in section 3.1 of the PRVD. The registrant indicated that the offspring NOAEL of 12.8 mg/kg bw/day based on the co-critical rat reproductive toxicity studies is not appropriate for derivation of the ARfD for tebufenozide since "drug intake during pregnancy/lactation is higher than the pre-cohabitation period that is 143–171 mg/kg bw/day".

Health Canada response

Health Canada agrees that the dog is the most sensitive species to tebufenozide-induced hematotoxicity based on the results of repeat-dose oral toxicity studies. However, the dog acute hematotoxicity study was not considered critical for derivation of the ARfD due to limitations in study design including the small number of endpoints examined, inclusion of a single sex (males), and lack of assessment in pregnant females and the young. Moreover, the NOAEL of 89.4 mg/kg bw/day derived from the dog acute hematotoxicity study is not adequately protective of the early postnatal loss in pups noted in the presence of maternal toxicity in two rat dietary reproductive toxicity studies. Offspring effects indicative of early postnatal loss in the first four days following birth were observed at the highest dose level tested in the reproductive toxicity studies (143 or 171 mg/kg bw/day), and included decreased F_1 pup viability index, decreased number of live F_2 pups/litter, and increased number of F_2 pups found dead. Although the offspring NOAELs were up to two orders of magnitude higher than the NOAELs for parental toxicity in each study, there is concern for the seriousness of the effects noted in offspring in these studies. Thus, the offspring NOAEL of 12.8 mg/kg bw/day, based on serious effects in the young in the two co-critical rat reproductive toxicity studies, is considered to be most appropriate for derivation of the ARfD for tebufenozide.

As per Health Canada regulatory practice, and in agreement with the USEPA (PMRA# 2834233) and European Food Safety Authority (PMRA# 2800997) reviews of the rat reproductive toxicity studies, offspring intake values in each study were based on F_0 maternal intakes during the premating period.

Therefore, contrary to the registrant's comment, the offspring NOAEL of 12.8 mg/kg bw/day is considered to be acceptable, and the method of derivation of the offspring dose levels is supported by the international regulatory community.

In conclusion, following critical analysis of the dog acute hematotoxicity study and the rat reproductive toxicity studies, Health Canada maintains that the offspring NOAEL of 12.8 mg/kg bw/day, based on early postnatal loss in two co-critical rat reproductive toxicity studies, is most appropriate for the derivation of the ARfD for tebufenozide.

2.0 Comments related to the environmental risk assessment

2.1 Comment

The registrant commented on spray buffer zones. They provided two new studies for consideration in the buffer zone calculations: an aerobic aquatic biotransformation study (PMRA# 3033477) and an aquatic mesocosm study (PMRA# 3033478). They requested that revisions to the required buffer zones be considered based on the new data.

Health Canada response

Health Canada reviewed both studies and found them to be acceptable. The studies were used to update buffer zone calculations as described in Section 2.0 Revised environmental risk assessment.

2.2 Comment

The registrant requested a clarification of label mitigation statements presented in Appendix V, page 84 "Buffer Zones". Is the following statement required only on the label for the products used in forestry (that is, Mimic 240LV Forestry Insecticide, Reg. No. 24502) and not on the agricultural label (that is, Confirm 240F Agricultural Insecticide, Reg. No. 24503).

> "BEFORE AERIAL APPLICATION TO FORESTS - Consult the most recent provincially approved topographic maps of the area to be treated (1: 50 000) or more up-to-date information (e.g., GPS Systems) to identify sensitive aquatic habitats. Sensitive aquatic habitats include: a) All running (lotic) and standing (lentic) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the map or GPS system; b) Running (lotic) and standing (lentic) water bodies that do not appear on the map or GPS system but are visible from the air."

Health Canada response

Health Canada confirms that this aerial forestry label statement is only needed on labels that include aerial application to forests (in other words, for this registrant, Mimic 240LV Forestry Insecticide, Reg. No. 24502).

3.0 Value assessment

No value comments were received during the tebufenozide consultation period. No changes required to the value assessment in PRVD2019-06.

Appendix IV Toxicology reference values for the human health risk assessment of tebufenozide

Exposure Scenario	Study	Point of Departure (POD) and Endpoint	CAF or Target MOE[1]
Acute Dietary	Co-critical multigeneration reproductive toxicity studies – rat	Offspring NOAEL = 12.8 mg/kg bw/day early postnatal loss (PND 0-4)	300
ARfD = 0.04 mg/kg bw			
Repeated Dietary	Co-critical 1-yr and 13-wk dietary toxicity studies – dog	NOAEL = 1.9 mg/kg bw/day hematotoxicity	100
ADI = 0.02 mg/kg bw/day			
Dermal Exposure (all durations)	21-day dermal toxicity study – rat	NOAEL= 1000 mg/kg bw/day no systemic effects at the limit dose	100
Inhalation Exposure (all durations)	Co-critical 1-yr and 13-wk dietary toxicity studies – dog	Oral NOAEL = 1.9 mg/kg bw/day hematotoxicity	100
Short- and Intermediate-Term Non-Dietary Incidental Oral Ingestion	Co-critical 1-yr and 13-wk dietary toxicity studies – dog	Oral NOAEL = 1.9 mg/kg bw/day hematotoxicity	100
Aggregate Risk (Oral, Inhalation)	Oral and Inhalation: Co-critical 1-yr and 13-wk dietary toxicity studies - dog	Common Endpoint: hematotoxicity Oral and Inhalation NOAEL = 1.9 mg/kg bw/day	100
Cumulative Risk **Tebufenozide and Methoxyfenozide**	Tebufenozide (Oral and Inhalation): Co-critical 1-yr and 13-wk dietary toxicity studies - dog Methoxyfenozide (Oral): 1-yr dietary toxicity study – dog	Common Endpoint: hematotoxicity Tebufenozide (Oral and Inhalation): NOAEL = 1.9 mg/kg bw/day Methoxyfenozide (Oral): NOAEL = 9.8 mg/kg bw/day	100
Cancer	No evidence of carcinogenicity in mice or rats.		

[1] CAF (Composite assessment factor) refers to the total uncertainty and PCPA factors for dietary and residential risk assessment; MOE refers to the target margin of exposure for occupational assessment.

Appendix V Label amendments for products containing tebufenozide

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

General label improvements:

1. On the principal display panel of all tebufenozide technical and end-use product labels, replace “Guarantee” with “Active ingredient”.
2. Update the resistance management statements on each end-use product label as per Regulatory Directive DIR2013-04, Pesticide Resistance Management Labelling Based on Target Site / Mode of Action.

I. Technical grade active ingredients

Remove the following statement under the **“PRECAUTIONS:’’**

“Do not contaminate any body of water.”

And **Replace with** the following statement:

- “DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.”

Replace the title **“ENVIRONMENTAL HAZARDS**”
with “**ENVIRONMENTAL PRECAUTIONS”**

Add the following statement to this section

- “TOXIC to aquatic organisms.”

Remove the following statement under the “**DISPOSAL AND DECONTAMINATION**”

Canadian formulators of this technical should dispose of unwanted active and containers in accordance with municipal or provincial regulations. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in the case of a spill, and for clean-up of spills.

And **Replace with** the following statement:

- “Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and cleanup of spills, contact the manufacturer or the provincial regulatory agency.”

II. Restricted class end-use products (registration no. 24502 and 32535)

Add to the Principal Display Panel:
"Group 18 Insecticides"

Under **PRECAUTIONS**:

Replace the following:
"Wear a cartridge respirator during ground-based applications."

With:

"Wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved canister approved for pesticides during ground-based applications. Chemical-resistant gloves and protective eyewear are not required during application within a closed cab and/or cockpit. Do not allow the pilot to handle and/or mix pesticide chemicals to be loaded onto the aircraft. Loading with a closed handling system is preferred."

Add to DIRECTIONS FOR USE:

"Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **Apply with rotary atomizers only. DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) very fine classification. Reduce drift caused by turbulent wingtip vortices. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Apply only by fixed-wing or rotary aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Use Precautions

Apply only when meteorological conditions at the treatment site allow for complete and even crop coverage. Apply only under conditions of good practice specific to aerial application as outlined in the National Aerial Pesticide Application Manual, developed by the Federal/Provincial/Territorial Committee on Pest Management and Pesticides.

Buffer zones:
BEFORE AERIAL APPLICATION TO FORESTS - Consult the most recent provincially approved topographic maps of the area to be treated (1: 50 000) or more up-to-date information (e.g., GPS Systems) to identify sensitive aquatic habitats.

Sensitive aquatic habitats include:

a) All running (lotic) and standing (lentic) water bodies, including impoundments, beaver ponds and bog ponds, that appear on the map or GPS system;
b) Running (lotic) and standing (lentic) water bodies that do not appear on the map or GPS system but are visible from the air."

III. Commercial class end-use products

Under **PRECAUTIONS**, the following updates must be included:

Replace the following:

"Wear protective clothing (long trousers, long-sleeved shirts), impervious gloves and splash goggles during all mixing, loading and application. Applicators must wear either a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides"

With:

"Wear long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), socks and footwear during all mixing, loading, application, clean-up, and repair. Applicators must wear either a respirator with a NIOSH approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH approved canister approved for pesticides. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."

Under **DIRECTIONS FOR USE**, the following update must be included:

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

Under **DIRECTIONS FOR USE,** the following label revisions are required:

- Clarify the application equipment by specifying the supported application equipment type, according to required risk mitigation measures.
- Add or revise the re-application interval, according to required risk mitigation measures.
- Add or revise the maximum number of applications per year, according to required risk mitigation measures.
- Add or revise the application rate for uses that have been modified to mitigate risk.

- Remove any reference to applications being applied "as needed", and replace with the supported re-application interval, or recommendations when to apply (for example, when conditions favour pest development).
- Replace minor use statements with the following (insert registrant name where indicated): "The DIRECTIONS FOR USE for the uses described in this section of the label were developed by persons other than [registrant name] under the User Requested Minor Use Label Expansion program. For these uses, [Registrant name] has not fully assessed performance (efficacy) and/or crop tolerance (phytotoxicity) under all environmental conditions or for all crop varieties when used in accordance with the label. The user should test the product on a small area first, under local conditions and using standard practices, to confirm the product is suitable for widespread application.
- Specify the list of supported pests.
- Add or revise the recommended water carrier volumes.

IV. ALL END-USE PRODUCTS

Replace the title **"ENVIRONMENTAL HAZARDS**"

With: "**ENVIRONMENTAL PRECAUTIONS"**

Add to "**ENVIRONMENTAL PRECAUTIONS**":

- "TOXIC to non-target aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

  To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

  Avoid application when heavy rain is forecast.

  Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

The following statement is required under the **STORAGE** heading:

- "To prevent contamination store this product away from food or feed."

Add to **GENERAL DIRECTIONS FOR USE**

- "As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests."

- "DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

Add to **DIRECTIONS FOR USE:**

- "Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground.

  Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

  Product specific precautions

  Read and understand the entire label before opening this product. If you have questions, call the manufacturer at (XXX)YYY-ZZZZ or obtain technical advice from the distributor or your provincial agricultural representative. Application of this specific product must meet and/or conform to the following:

  Volume: Apply the recommended rate in a minimum spray volume of 1.5 litres per hectare.

  Buffer zones:

  Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

  The buffer zones specified in Table 1 below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Table 1 Aquatic Buffer Zones Required During Tebufenozide Use Near Water

Method of application	Crop		Buffer Zones (metres) Required for the Protection of: Freshwater Habitat of Depths: Less than 1 m	Greater than 1 m
Field sprayer	Cranberry and Bushberry subgroup 13-07B: *Highbush blueberry, Lowbush blueberry, Black currant, Elderberry, Gooseberry, Huckleberry, Aronia berry, Buffalo currant, Chilean guava, European barberry, Highbush cranberry, Edible honeysuckle, Jostaberry, Juneberry (Saskatoon berry), Lingonberry, Native currant, Salal, Sea buckthorn*		3	2
Airblast	Cranberry and Bushberry subgroup 13-07B: *Highbush blueberry, Lowbush blueberry, Black currant, Elderberry, Gooseberry, Huckleberry, Aronia berry, Buffalo currant, Chilean guava, European barberry, Highbush cranberry, Edible honeysuckle, Jostaberry, Juneberry (Saskatoon berry), Lingonberry, Native currant, Salal, Sea buckthorn*	Early growth stage	15	5
		Late growth stage	5	3
	Apple, pear, ornamental crab apple tree	Early growth stage	15	5
		Late growth stage	5	2

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site."

Appendix VI References Considered Following Publication of PRVD2010-06

Note that the following includes only references that were not previously considered in PRVD2019-06.

A. Information considered in the updated environmental assessment

List of studies/information submitted by registrant

PMRA Doc. Number	Title
1172878	1997, RH-5992: Chronic effects on midge larvae (*Chironomus riparius*) in a water/sediment system, DACO: 9.3.4
3033477	2002, 14C-RH-75,992: Route and Rate of Degradation in Aquatic Systems, DACO: 8.2.3.5.4
3033478	2017, Tebufenozide - Outdoor aquatic mesocosm study, DACO: 8.2.3.6